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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,733	09/14/2001	Patrick John Thompson Vallance	117-358	9066

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EXAMINER	
PRIEBE, SCOTT DAVID	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 09/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/889,733	VALLANCE ET AL.	
	Examiner	Art Unit	
	Scott D. Priebe	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *46-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *46-70* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Groups I-VI, claim(s) 46-48, 50-53, 66, drawn to a polynucleotide encoding a methylarginase selected from human DDAHI (group I); human DDAHII (group II); *Streptomyces coelicolor* DDAH (group III); *Pseudomonas aeruginosa* DDAH (group IV); *P. aeruginosa* arginine deaminase (group V); and *Mycobacterium tuberculosis* DDAH (group VI), respectively, and the first claimed method of using each, which is to prepare a methylarginase from cultured cells.

Groups VII-XII, claim(s) 49, 64-66, drawn to a methylarginase selected from human DDAHI (group VII); human DDAHII (group VIII); *Streptomyces coelicolor* DDAH (group IX); *Pseudomonas aeruginosa* DDAH (group X); *P. aeruginosa* arginine deaminase (group XI); and *Mycobacterium tuberculosis* DDAH (group XII), respectively, and the first claimed method of using each, which is to identify modulators of methylarginase activity.

Groups XIII-XVIII, claim(s) 54, drawn to an antibody which binds a methylarginase selected from human DDAHI (group XIII); human DDAHII (group XIV); *Streptomyces coelicolor* DDAH (group XV); *Pseudomonas aeruginosa* DDAH (group XVI); *P. aeruginosa* arginine deaminase (group XVII); and *Mycobacterium tuberculosis* DDAH (group XVIII), respectively.

Group XIX, claim(s) 55-58, drawn to a non-human animal which does not express DDAHI.

Group XX, claim(s) 55-58, drawn to a non-human animal which does not express DDAHII.

Group XXI, claim(s) 59, 60, 63-66, drawn to a compound which inhibits expression of a methylarginase, and the first claimed method of using the compound, which is to identify inhibitors of expression of a methylarginase.

Group XXII, claim(s) 59, 61, 63-66, drawn to a compound which activates expression of a methylarginase, and the first claimed method of using the compound, which is to identify activators of expression of a methylarginase.

Group XXIII, claim(s) 59, 60, 62, 63-66, drawn to a compound which inhibits a methylarginase, and the first claimed method of using the compound, which is to identify inhibitors of a methylarginase.

Group XXIV, claim(s) 59, 61, 63-66, drawn to a compound which activates a methylarginase, and the first claimed method of using the compound, which is to identify activators of a methylarginase.

Group XXV-XXX, claim(s) 64, 65, drawn to the second claimed method of using a polynucleotide encoding a methylarginase selected from human DDAHI (group XXV); human DDAHII (group XXVI); *Streptomyces coelicolor* DDAH (group XXVII); *Pseudomonas aeruginosa* DDAH (group XXVII); *P. aeruginosa* arginine deaminase (group XXIX); and *Mycobacterium tuberculosis* DDAH (group XXX), respectively, which is in an assay to identify modulators of expression of each methylarginase.

Group XXXI-XXXVI, claim(s) 64, 65, drawn to the third claimed method of using a polynucleotide encoding a methylarginase selected from human DDAHI (group XXXI); human DDAHII (group XXXII); *Streptomyces coelicolor* DDAH (group XXXIII); *Pseudomonas aeruginosa* DDAH (group XXXIV); *P. aeruginosa* arginine deaminase (group XXXV); and *Mycobacterium tuberculosis* DDAH (group XXXVI), respectively, which is in an assay to identify modulators of the activity of each methylarginase.

Group XXXVII-XLII, claim(s) 67, drawn to the second claimed method of using a methylarginase selected from human DDAHI (group XXXVII); human DDAHII (group XXXVIII); *Streptomyces coelicolor* DDAH (group XXXIX); *Pseudomonas aeruginosa* DDAH

(group XL); *P. aeruginosa* arginine deaminase (group XLI); and *Mycobacterium tuberculosis* DDAH (group XLII), respectively, which is in a method of treating a human or animal.

Group XLIII-XLVIII, claim(s) 67, drawn to the fourth claimed method of using a polynucleotide encoding a methylarginase selected from human DDAHI (group XXXI); human DDAHII (group XXXII); *Streptomyces coelicolor* DDAH (group XXXIII); *Pseudomonas aeruginosa* DDAH (group XXXIV); *P. aeruginosa* arginine deaminase (group XXXV); and *Mycobacterium tuberculosis* DDAH (group XXXVI), respectively, which is in a method of treating a human or animal.

Group IL, claim(s) 67-70, drawn to the second claimed method of using a compound that inhibits expression of a methylarginase, which is in a method of treating a human or animal.

Group L, claim(s) 67-70, drawn to the second claimed method of using a compound that inhibits a methylarginase, which is in a method of treating a human or animal.

The inventions listed as Groups I-L do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups I-VI are each directed to a polynucleotide that encodes a structurally different methylarginase, isolated from a different source. Methylarginases were known in the prior art, as indicated in the specification, so while this is a shared technical feature, it is not a special

technical feature. The specification also admits prior art was identified for polynucleotides encoding the DDAH of *S. coelicolor* and *M. tuberculosis* (see page 35, lines 5-16), and the human DDAHI and DDAHII (see page 39, lines 13-27). Similarly, the polypeptides of groups VII-XII or antibodies of groups XIII-XVIII lack a shared special technical feature.

Groups I-VI (polynucleotides), VII-XII (polypeptides), XIII-XVIII (antibodies), and the different classes of "modulators" (Groups XXI-XXIV) are drawn to structurally and functionally different class of molecules and thus do not share a technical feature, much less a special technical feature. The non-human transgenic animals of Groups XIX and XX lack the polynucleotides or polypeptides of groups I and II, respectively, or lack a methylarginase not included in groups VII-XII. It is noted that most any prior art transgenic animal would lack a bacterial methylarginase, and so would read on claim 55.

Groups XXV-L are directed to one or more additional methods of using the compounds of Groups I-XVIII, or XXI-XXIV. Each of these additional methods differs from the first claimed methods of using each of the compounds in terms of the other products used in the methods and/or the goal of the methods.

Multiple distinct products or multiple distinct methods of using a product are not recognized as sharing unity of invention under 37 CFR 1.475.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (703) 308-7310. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Scott D. Priebe
Primary Examiner
Art Unit 1632